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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,667	01/13/2009	Paul Rufo	C0875.70019US02	4608

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EXAMINER	
ZAREK, PAUL E	

ART UNIT	PAPER NUMBER
1628	

MAIL DATE	DELIVERY MODE
05/06/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,667	RUFO ET AL.	
	Examiner	Art Unit	
	Paul Zarek	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/16/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1, 2, 6, and 10 have been amended and Claims 13-44 have been cancelled by the Applicant in correspondence filed on 02/16/2010. Claims 1-12 are currently pending. This is the second Office Action on the merits of the claim(s).

RESPONSE TO ARGUMENTS

2. Applicants are correct that Examiner acknowledged Applicants' election of Group I in reply filed on 07/22/2009. Examiner's statement regarding "Group II" was a typographical error which Examiner regrets.

3. Examiner acknowledges Applicants' submission of Supplemental Application Data Sheet and Amendment to the Specification to claim the benefit of the prior-filed provisional application no. 60/504,516. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be

accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

4. In the instant application, Applicants are attempting to claim the benefit of the prior-filed provisional application after the required time period (the later of four months after filing of instant application or 16 months after filing of the prior application. Therefore, the effective filing date of the instant application is 09/20/004. Examiner notes that none of the originally filed documents indicate the intent to claim the benefit of provisional application no 60/504,516. Thus, Applicants must file a petition to be granted the benefit of the filing date of the provisional application.

5. Claims 1, 3-5, 7-9, 11, and 12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mimura, et al. (Alimentary Pharmacology and Therapeutics, 2002). The rejection under 102(b) is moot in light of Applicants' amendment to Claim 1.

6. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mimura, et al. (above). Applicants traversed this rejection on the grounds that Mimura, et al., do not teach

or fairly suggest the instant invention. Specifically, Applicants contend that Mimura, et al., do not teach administering more than 400 or 500 mg of metronidazole tablets twice a day (b.i.d.) and assert that it was known at the time of filing that high conventional dosing of anti-fungal azole compounds were associated with undesired side effects. Thus, Applicants argue that one of ordinary skill in the art would not be motivated to administer 2,000-10,000 mg anti-fungal azole compounds to treat pouchitis. Applicants further argue that Examiner has not provided any factual support that direct application of the claimed dosage of azole compounds to the distal intestinal tract would be tolerated and/or effective to treat pouchitis. Respectfully, Examiner does not find Applicants' arguments persuasive.

7. Mimura, et al., teach that antibiotics, such as metronidazole, are effective for the treatment of pouchitis (pg 910, col 2, para 4, lines 1-2). Pouchitis can result from restorative proctocolectomy with ileal pouch anal anastomosis (pg 910, col 1, para 1, lines 8-10). Metronidazole is an anti-fungal imidazole compound. Mimura, et al., disclose treating human patients suffering pouchitis with metronidazole and ciprofloxacin, an anti-bacterial compound (pg 911, col 2, para 2, lines 1-4). Metronidazole and ciprofloxacin were administered as tablets and, although not explicitly disclosed, said tablets are interpreted by Examiner to be administered orally. During oral administration of metronidazole and ciprofloxacin some of the drugs would fail to be absorbed and would thus be locally administered to the distal intestinal tract. Applicants have not disagreed with Examiner's interpretation of Mimura, et al.

8. Applicants amended Claim 1 to limit the amount of anti-fungal azole compound administered to between 2,000 mg and 10,000 mg. Examiner notes that no time limitation is present in the claims. The method taught by Mimura, et al., includes administration of 400 or

500 mg of metronidazole b.i.d. for 28 days. This method necessarily includes administration of 2,000 mg of metronidazole in 2.5 days (400 mg) or 2 days (500 mg), and 10,000 in 12.5 days (400 mg) or 10 days (500 mg). Thus, one of skill in the art would readily recognize 2,000 to 10,000 mg metronidazole is both tolerated and effective for the treatment of pouchitis. Moreover, Tracy and Webster (Goodman & Gilman's The Pharmacological Basis of Therapeutics, 10th ed. 2001) teach that a single daily dose of 2,000 mg (2 g) of metronidazole for three days or 750 mg given three times a day (2250 mg total) for up to 10 days is tolerated (pg 1107, section "Therapeutic Uses"). Tracy and Webster further state that "side effects are only rarely severe enough to discontinue therapy (pg 1108, col 1, para 1, lines 1-2). Thus, Tracy and Webster teach that metronidazole is well tolerated at the doses of the instant invention, and one of skill in the art would not be dissuaded from using such doses precisely because they are indicated for some infections.

9. For the above reasons, the rejection of Claims 1-12 under 35 U.S.C. 103(a) as being unpatentable over Mimura, et al., is maintained. Applicants' amendments are not sufficient to overcome this rejection.

Conclusion

10. Claims 1-12 remain rejected.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/San-ming Hui/
Primary Examiner, Art Unit 1628